CMS finalizes new exceptions and clarifications to Stark Law

November 10, 2015

On October 30, 2015, the Centers for Medicare & Medicaid Services (CMS) issued the final CY 2016 Physician Fee Schedule rule (the Final Rule), which includes new exceptions and several helpful clarifications to the Stark regulations. The Final Rule updates the Stark regulations to accommodate delivery and payment system reforms, reduce burden and facilitate compliance. The Final Rule will be published in the Federal Register on November 16 and becomes effective January 1, 2016.

New Exceptions

Recruitment of Non-Physician Practitioners. Due to changes in health care delivery and the projected shortages in primary care providers, CMS finalized a new exception for remuneration from a hospital, federally qualified health center (FQHC) or rural health center (RHC) to a physician to assist the physician in compensating an employee or independent contractor non-physician practitioner (NPP) who furnishes substantially all primary care services or mental health services to patients of a physician's practice. For purpose of the new exception, NPPs include clinical social workers, clinical psychologists, physician assistants, nurse practitioners, clinical nurse specialists and certified nurse midwives. NPPs do not include certified registered nurse anesthetists, dieticians and physical therapists, however. The amount of the remuneration may not exceed 50 percent of the actual aggregate compensation to the NPP (including any signing bonus and benefits). The exception may be used only once in a three year period for the same physician. In addition, the exception is not available for indirect compensation arrangements, which must satisfy the indirect compensation arrangement exception. For example, the exception cannot be used to provide assistance to a physician who contracts with a staffing company that will provide an NPP to the physician's practice.

Timeshare Arrangements. CMS finalized a new exception to protect timeshare arrangements between hospitals or physician organizations (a licensor) and physicians for the non-exclusive use of the hospital's or physician organization's space, equipment, personnel, supplies or services if they meet specified requirements, including:

- The arrangement specifies the equipment, personnel, supplies or services and is in writing, signed by the parties;
- Compensation is set in advance, consistent with fair market value and commercially reasonable and does not take into account the volume or value of referrals;
- Compensation does not use a formula based on a percentage of revenue raised, earned, billed, collected or otherwise attributed to the services provided or a formula based on a per-unit of service fee that is not time based if the fees are for services referred to the licensor or the licensee;
- The premises are used primarily for evaluation and management (E/M) services and any equipment is located in the same building where the E/M services and designated health services (DHS) are furnished; and
- All locations included in the arrangement for furnishing E/M and DHS services must have identical schedules.

CMS finalized the new exception to address concerns that timeshare arrangements, while fairly common and beneficial in some circumstances, could generally not satisfy existing exceptions. For example, they often cannot meet the space and equipment arrangement exceptions, which require "exclusive use" when used by the lessee, or the fair market value exception, which is not available for space leases.

Clarifications

The Final Rule includes the following clarifications and modifications to existing Stark exceptions.

Written Agreement Requirement. Clarifies that exceptions requiring a writing can be met if there are multiple documents evidencing an agreement. For example, a collection of documents reflecting the course of conduct between the parties may suffice if they would permit a reasonable person to verify compliance with the exception.

Definition of Remuneration. Clarifies that an exclusion from remuneration is available only for items, devices or supplies (other than surgical) that are used solely for the specified purposes of collecting, transporting, processing or storing specimens, ordering tests or procedures, or communicating test or procedure results. CMS also clarified (without making any change in the regulation) that arrangements involving split billing, in which a hospital and a physician bill independently for their services furnished to hospital patients at a hospital-based location, do not involve remuneration or create a compensation arrangement.   As a result, these split billing arrangements do not need to meet a Stark exception. However, CMS viewed global billing arrangements, in which for example a hospital bills globally for services furnished by both the hospital and the physician at a hospital location, as involving remuneration because the billing party would receive reimbursement for the services of the other party. These arrangements must meet a

Stark exception, such as the personal services, fair market value, space or equipment lease exceptions. CMS did not clarify whether exclusive contracts for physicians to furnish professional services to hospital patients may result in remuneration even if billing is split, however.

One Year Term Requirement. Clarifies that the term of a lease or personal services arrangement does not need to be stated in writing in the agreement if the arrangement in fact continues for one year and complies with all other requirements of the applicable exception. Because this is a clarification of an existing requirement, it applies to arrangements that existed before the effective date of the Final Rule.

Temporary Noncompliance with Signature. Changes the grace period in which to obtain missing signatures to 90 days whether the lack of signature was inadvertent or advertent.

Holdover Arrangements for Space, Equipment and Personal Services. Modifies the space, equipment and personal services exceptions to allow holdovers of expired agreements indefinitely if they continue on the same terms and are otherwise compliant with the exception.

Fair Market Value. Permits renewals of arrangements using the fair market value exception for any length of time on the same terms. However, the failure to charge a holdover penalty or compensation increase stated in the agreement would be viewed as a change in terms.

Meaning of “Takes Into Account.” Replaces nonconforming language in all compensation exceptions to use the term “takes into account” the volume or value of referrals.

“Stand in the Shoes.” Clarifies that only physicians with an ownership or investment interest in their physician organizations or who voluntarily elect to stand in the shoes of their physician organization “stand in the shoes” with respect to the Stark signature requirements. However, all physicians in a physician organization (including members, employees and independent contractors) are parties to the compensation arrangement for all purposes other than the signature requirements, including the prohibition on taking into account referrals and other business generated between the parties.

“Incident To.” Modifies the definition of “incident to” billing to require the billing physician to also be the physician who directly supervises the personnel who provide the incident to services and to prohibit incident to billing for any services furnished by auxiliary personnel who have been excluded from Medicare, Medicaid or other federal health care programs. These changes would impact Stark requirements that involve incident to billing, such as a group practice’s payment of productivity bonuses.

Exception for Ownership in Publicly Traded Securities. Modernizes the exception to protect ownership or investment interests in securities listed for trading on an electronic stock market or over the counter quotation system if the quotations are published on a daily basis and the trades are standardized and publicly transparent. Ownership or investment interests in electronic stock markets or over the counter quotation systems that trade unlisted stocks or that involve decentralized dealer networks are not protected, however.

Geographic Area Served by Rural Health Centers and Federally Qualified Health Centers. For purposes of the physician recruitment exception, defined “geographic area served by an FQHC or RHC” as the lowest number of contiguous or noncontiguous zip codes comprising 90 percent of patients as determined on an encounter basis.

Retention of Payments in Underserved Areas. Modifies the exception to clarify that a retention payment based on a physician’s certification cannot exceed an amount equal to 25 percent of the physician’s current annual income, averaged over the entire previous 24 months.

In addition to the above new exceptions and clarifications, CMS is planning to issue a report to Congress to determine if additional rulemaking may be necessary in light of evolving payment models integrating physicians and other health care entities to achieve population health and reduce costs.

